



A Company of Sysmex Group



HYPHEN BioMed  
155 rue d'Eragny  
95000 Neuville-sur-Oise  
France

### CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN HEPARIN CALIBRATOR  
**Product Code :** 222001  
**Lot No. :** FC00161F  
**Expiration date :** 2025-06-24

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FC0016BJ1F	2025-06-24
CAL 2	4 vials	FC0016BK1F	2025-06-24
CAL 3	4 vials	FC0016BL1F	2025-06-24
CAL 4	4 vials	FC0016BM1F	2025-06-24
CAL 5	4 vials	FC0016BN1F	2025-06-24

Analytical Data	Specification	Result
Concentration	CAL 1 : $\leq 0.05$ IU/ml CAL 2 : 0.30 -0.50 IU/ml CAL 3 : 0.70 -0.90 IU/ml CAL 4 : 1.10 -1.30 IU/ml CAL 5 : 1.45 -1.75 IU/ml	0 IU/mL 0.37 IU/mL 0.77 IU/mL 1.14 IU/mL 1.51 IU/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval : 2023-01-19

Quality Control Manager : **S.LECOURT**